



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

M21357

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

October 28, 1998

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Richard Alexander, President
Sure Nutrition
901 E. Pennsylvania BLVD
Feasterville, PA 19053

Dear Mr. Alexander:

During an inspection of your firm, Sure Nutrition, located at 901 East Pennsylvania Boulevard in Feasterville, PA, on December 17 and 18, 1997, Food and Drug Administration (FDA) investigators Anthony A. Charity and Micheal R. Tally documented that you are engaged in the manufacture and distribution of Cough Free, a veterinary equine drug product. Labeling distributed with Cough Free states or suggests that the product is useful in treating or preventing various disease conditions in horses such as infections, fevers, allergies, asthma, bronchitis, coughs, sore throat and lungs, and intestinal wounds/ulcers. Promotional material and your firm's catalog also include the above-referenced medical/therapeutic claims for Cough Free.

Under the Food, Drug, and Cosmetic Act (the Act), any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, or intended to effect the structure or function of man or other animal, is regarded as a "drug". Unless a drug is generally recognized as safe and effective for its labeled uses, it is a new animal drug under the law. A new animal drug may not be legally marketed unless it is the subject of an approved New Animal Drug Application (NADA). Because labeling distributed with Cough Free includes statements which represent and suggest this product is intended to be used in the cure, mitigation, treatment, or prevention of disease, Cough Free is an animal drug within the meaning of Section 201(v)(1) of the Federal Food, Drug, and Cosmetic Act (the Act). Further, we are unaware of any substantial scientific evidence which documents that this product is generally recognized as safe and effective for the above-referenced disease condition(s) or any other disease condition(s). Therefore, Cough Free is adulterated under Section 501 (a)(5) of the Act.

Our Center for Veterinary Medicine (CVM) has also reviewed objectionable therapeutic and structure/function claims on product labels and promotional materials for the following equine products manufactured and distributed by your firm. These veterinary products are considered "drugs" and "new animal drugs" which are adulterated under Section 501(a)(5) of the Act for their labeled therapeutic and structure/function claims as follows:

SUREFLEX

Helps keep synovial fluids thick and elastic, holding ligaments and muscles firm and sound, preventing inflammation during stressful training and competition;

Thickens the viscosity of the horses joint lubricants, explaining its ability to relieve swelling and stiffness;

Maintains synovial fluid viscosity, important for lubrication of bone joint linings;

Relief from pain and stiffness associated with degenerative joint disease;

Extremely beneficial for expediting body repair as seen in illness, injury or trauma;

Effective in healing soft tissue, torn tendons, and bruises.

Sure Tite

Relieves swelling fast, temporary relief of inflammation and soreness.

MSM

Improves circulation fast.

Biotin

Promotes hoof and bone growth;

Beneficial for horses with chronic foot problems.

DMG

Helps in reducing lactic acid build up, which causes premature fatigue and tie ups;

Improves delivery of oxygen to muscle.

SureLytes

Absorbs into muscle and therefore aids in tie ups;

Helps restore fluids that horses lose during training.

SureESE Powder

Remedy for muscle buildup and eliminates muscle soreness in horses that train hard.

Unsubstantiated drug claims in promotional materials can misbrand your products. The products SureFlex, Sure Tite, MSM, Biotin, DMG, SureLytes, and SureESE Powder are not generally recognized as safe and effective for their promotional drug claims. Therefore, these veterinary products are considered misbranded.

The above is not intended to be an all-inclusive list of violations which may exist at your firm. As top management, it is your responsibility to ensure that all veterinary drug products your firm manufactures and/or distributes are in compliance with all the requirements of the Food, Drug, and Cosmetic Act.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This includes seizure and/or injunction.

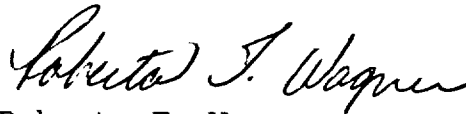
Please advise this office in writing within fifteen (15) days of receipt of this letter as to the specific actions you have taken or intend to take to correct the violations associated with Cough Free and the other veterinary products referenced above. If corrective action cannot be completed within 15 days, provide the reason for the delay and the timeframe you expect correction to be implemented. Also include any available documentation

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demonstrating that corrective action has been made.

Your reply should be directed to the attention of James C. Illuminati, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in cursive script, appearing to read "Roberta F. Wagner".

Roberta F. Wagner
Acting District Director
Philadelphia District

jci

cc: PA Department of Health
Health & Welfare Building, Room 1032A
7th & Forster Streets, P.O. Box 90
Harrisburg, PA 17120
Attention: Division of Primary Care & Home Health Services
Robert E. Bastian, Director